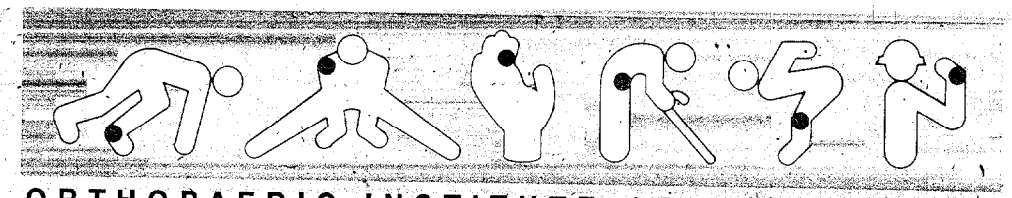

**ORTHOPAEDIC INSTITUTE OF DAYTON, INC.**

December 17, 1999

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Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket number 97N-484S

To whom it may concern:

I am writing this letter in response to the recent issue arising before the FDA on the proposal to regulate allografts, specifically cortical bone dowels as devices.

I am against any re-classification of bone dowels as devices. Bone dowels have been out for quite some time and they fall well within the conceptual standard of care of interbody fusions that have been done for a number of years. Interbody fusions with allografts have been done for quite some time, and I don't think regulating allografts at this time would serve any useful purpose for patients.

Allograft bone is used in multiple different settings in the spine and in other orthopaedic procedures. Creating a new regulatory classification scheme that allograft is in some way a device will only serve to make allograft less readily obtainable, more costly, and will ultimately hurt patient care. Allograft bone dowels are, like all allograft use, a very natural, i.e., nonsynthetic product, and I feel, as do many spine surgeons, far safer and better to use than metal devices. I think the ability to continue to use allograft and its free availability is very important to my practice and to patients.

Sincerely,

Marcos E. Amongero, M.D.
MEA:mms/58

File: 1617mea

97N 484S

DICTATED BUT NOT READ

C147


**Pietro Seni, M.D., FACS***
- Total Joint Replacement
- Foot & Ankle Reconstructive Surgery

**Frank P. Mannarino, M.D.***
- Knee Surgery & Sports Medicine

**Richard W. Forster, M.D., FRCS***
- Total Joint Replacement

**Paul A. Nitz, M.D.***
- Shoulder & Knee Surgery & Sports Medicine

**Steve J. Gabel, M.D.***
- Foot and Ankle Reconstructive Surgery

**Marcos E. Amongero, M.D.***
- Surgery of the Spine

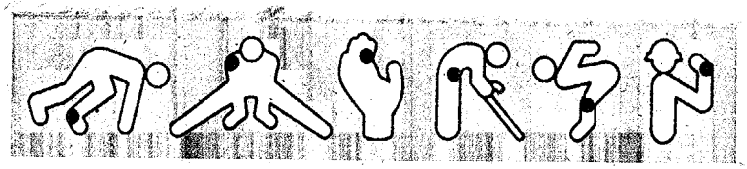
**Gene C. Kim, M.D.**
- Hand Surgery

**Barry A. Fisher, M.D.**
- Primary Care Sports Medicine

*Certified by the American Board of Orthopaedic Surgery

3205 Woodman Drive
Dayton, Ohio 45420

**937/298-4417**
**FAX: 937/298-8260**
**Web Site http://www.rosi.com/**



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